REMARKS

Claims 1-50 are pending. Claims 1-8, 12 and 13 were examined and stand rejected in the final Office Action mailed February 4, 2009. Applicants respond below to the specific rejections set forth in the final Office Action. For the reasons set forth below, Applicants respectfully traverse.

Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 1-7, 12 and 13 as allegedly being unpatentably obvious over U.S. Patent Application Publication No. 2002/0086065 to Katz et al., in view of Godsland et al. (1992) *J. Endocrinol. Metab.* 74(1):64-70. The Examiner has also rejected Claim 8 under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Katz et al. and Godsland et al., in further view of Goodman and Gillman's, (1995) *The Pharmacological Basis of Therapeutics* 8th Edition. The Examiner states that Katz et al. teach a method of decreasing insulin resistance comprising administering chromium picolinate at a daily dose of 1,000μg/day, but that Katz et al. does not teach the step of identifying an individual receiving a dose of a drug, *e.g.*, an oral contraceptive, that induces insulin resistance and contemporaneously administering chromium picolinate to the individual. The Examiner asserts that Godsland et al. teach that oral contraceptive drugs cause insulin resistance. As such, the Examiner argues that "it would have been *prima facie* obvious to one of ordinary skilled in the art at the time . . . to identify an individual receiving a dose of a drug that induces insulin resistance . . . and then to administer chromium picolinate contemporaneously . . . with said drug to alleviate/reduce a known side effect of the drug since oral contraceptives were known to cause insulin resistance and chromium picolinate was known to treat insulin resistance . . . thus resulting in the practice of the instantly claimed invention." *Office Action* at 3-4. Regarding Claim 8, the Examiner states that Goodman and Gillman teach the parenteral administration of drugs, and thus asserts that it would have been obvious to parenterally administer a chromium complex to an individual as in Claim 1. Applicants respectfully traverse.

To establish a *prima facie* case of obviousness, the Examiner must establish that the prior art reference (or references when combined) teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also M.P.E.P.*

§ 2143.03. Further, another requisite element in establishing a *prima facie* case of obviousness is the establishment that the skilled artisan would have a reasonable expectation of success in practicing the claimed invention. *See,* M.P.E.P. §2143.02 "Reasonable Expectation of Success is Required." Whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. See, *Ex parte Erlich*, 3 USPQ2d 1011 (BPAI 1986).

Applicants maintain that the final Office Action does not set forth a *prima facie* case of obviousness under 35 U.S.C. § 103(a) since there is no indication in the references that chromium complexes can be used in a prophylactic manner to "inhibit[] the development of insulin resistance," as recited in Applicants' claims, and the skilled artisan would not have a reasonable expectation of preventing the onset of insulin resistance, given the teachings of the cited art.

Claims 1-7, 12 and 13 are directed to methods of *inhibiting the development* of drug-induced *insulin resistance* by administering an amount of chromium complex sufficient to *inhibit the development* of *insulin resistance*. Thus Applicants' claims are limited to the prevention of the development of insulin resistance and diseases secondary thereto, in the first place. As such, Applicants' claimed invention prevents subjects from being exposed to insulin resistance-associated diseases and risks, or having to undergo additional costly therapy for the treatment of insulin resistance (or related secondary diseases). *Specification* at paragraph [0028].

The primary reference relied upon in the Examiner's rejection under 35 U.S.C. § 103(a), *i.e.*, Katz et al., does not teach the prevention of insulin resistance, as recited in Claims 1-7, 12 and 13. Rather, Katz et al. relate to the treatment of a pre-existing condition, *i.e.*, polycystic ovary syndrome, and symptoms associated with PCOS. *Katz* et al. at [0068], [0090], and Claim 1. Katz et al. teach that "the hallmark features of PCOS are obesity, insulin resistance, abnormal lipid profile, excessive hair growth, anovulation, and infertility." *Id.* at [0006]. The methods disclosed in Katz et al. involve the identification of a patient suffering from PCOS, and administration of an "effective dose" of at least one chromium complex. *Id.* The effective dose is a dose that "treats or reduces" at least one symptom of PCOS. Katz et al. do not teach that chromium supplementation is useful to prevent the onset (*i.e.*, individuals who do not even have), insulin resistance. In fact, nothing in Katz et al. would lead the skilled artisan to expect

that chromium complexes can be used to prevent the development of any condition, including insulin resistance.

The methods of Claims 1-7, 12 and 13, in contrast to the methods of Katz et al. serve a prophylactic purpose, *i.e.*, to prevent the onset of insulin resistance. The present claims are based on the discovery that administration of chromium complex prior to, or concomitantly with, certain drugs prevents individuals from ever developing insulin resistance. In contrast to using chromium supplementation for individuals with PCOS, the methods of the present claims involve the administration of a chromium complex to individuals that have not yet developed insulin resistance. Accordingly, since Katz et al. fail to teach inhibition of the development of insulin resistance, and since the teaching of Katz et al. would not provide the skilled artisan with a reasonable expectation of success, Katz et al. do not support a *prima facie* case of obviousness.

Godsland et al. suffer from the same deficiencies as Katz et al., and thus do not support a *prima facie* case under 35 U.S.C. § 103(a), either alone or in combination with Katz et al. Specifically, nothing in Godsland et al. relates to the inhibition of the development of insulin resistance. The Examiner relies upon the teachings of Godsland et al. solely for the proposition that oral contraceptives cause insulin resistance. Godsland et al. is completely silent regarding the inhibition of the development of insulin resistance, except for providing the suggestion that the use of alternative estrogens should be considered as a potential means to reduce the metabolic side effects of oral contraceptives. *Godsland* et al., p. 69, Col 2. Nothing in Godsland et al., however, would lead the skilled artisan to administer chromium complexes to an individual, for any reason, including the inhibition of the development of insulin resistance. Accordingly, Godsland et al. do not cure the deficiencies in the teachings of Katz et al. discussed above. Godsland et al., either alone or in combination with the teachings of Katz et al., do not support a *prima facie* case of obviousness under 35 U.S.C. § 35 U.S.C. § 103(a).

The teachings of Goodman and Gillman's, relied upon by the Examiner in the rejection of Claim 8 are limited to the route of administration of therapeutics. Thus, the rejection of Claim 8 should be withdrawn for the reasons set forth above relating to Claims 1-7, 12 and 13.

Applicants submit that for the foregoing reasons, the Office Action does not set forth a *prima facie* case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 1-8, 12 and 13 under 35 U.S.C. § 103(a).

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

The undersigned has made a good faith effort to respond to the Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to call the undersigned attorney to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: April 2, 2009

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